

| MAJOR COMMENTS BNFL QAPIP, REVISION 4A | | |
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| ITEM NO. | REGULATORY UNIT COMMENTS | RESOLUTION BY BNFL |
| 1. | <p>General Comment – Several subsections (e.g., 5.3 and 7.2) had major changes that were apparently included to incorporate QARD requirements. These sections appeared to cite the requirements verbatim, and do not describe the following:</p> <ul style="list-style-type: none"> • What actions BNFL plans to take in order to comply with these requirements, and • Who is responsible for performing the actions. <p>In addition, the Regulatory Unit is concerned that BNFL may not have implementing procedures or codes of practice in place to describe details on how the above actions will be completed.</p> | <p>These sections were incorporated to identify and meet QARD requirements. The sections have been revised to include project-related actions.</p> <ul style="list-style-type: none"> • BNFL will provide implementing documents as required under Section 5, Work processes. • Responsibilities are consolidated in Appendix A and provide adequate authority and responsibility assignments for the activity. • The RU concern that BNFL may not have implementing documents is noted. Appendix B provides the requirement for implementing document completion activity. As described in Section 5, work processes are accomplished in accordance to written instructions. |
| 2. | <p>Introduction – Currently, the Regulatory Unit has approved the QAPIP for only pre-construction activities. This draft of the QAPIP was submitted to the Regulatory Unit as the annual revision, and not as the QAPIP for the construction phase. Thus, deletion of the words ". . . until the start of construction" is confusing and misleading.</p> <p>Nine project activities or "phases" are listed in Table A-1 of the Implementation Plan, and the first paragraph of Section 2 of the Implementation Plan refers to ensuring ". . . the quality of work for the design stage of Part B . . .". However, the Implementation Plan does not clearly indicate which (if any other than preliminary design and detailed design) of the nine project activities or "phases" are within the scope of the QAPIP.</p> <p>BNFL should clearly indicate in Table A-1 of the Implementation Plan what project activities or phases are within the scope of the QAPIP, and provide the schedule for the next QAPIP revision.</p> | <p>The QAPIP is written to perform work in Part B1 of the contract. The contract requires a QAPIP revision prior to construction and thus this submittal as stated is an annual revision and not the construction submittal. The requirement for the QAP is 10 CFR 830.120 from the contract. The contract is an upper tier requirement for the quality program and as such the wording is not misleading or confusing.</p> <p>Table A-1 has been revised to include additional headings for the Part B1 activities. The schedule for QAPIP revision is included in Section 3 of Appendix B.</p> |

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| 3. | <p>PROJECT QUALITY POLICY, fifth paragraph – Revision 4 committed to NQA-1-1994, Part 2 in addition to Part 1. Did BNFL mean this as a lessening of requirements, or as merely a typographical error? Since both Parts 1 and 2 of NQA-1-1994 are specified as "requirements", we suggest that the policy (and subsequent text thereafter) should refer to " . . . the applicable requirements of . . . NQA-1-1994, Parts 1 and 2 . . .".</p> | <p>Revision 4 of the QAP clearly stated in Table 1-1 the compliance to ASME NQA-1. In addition, Section 12, References, the reference to NQA-1 is for ASME NQA-1, 1994a, Part1. Additional NQA-1 references are for applicable supplements. The basic requirements of ASME NQA-1, Part 1 (1994) are what was stated. See note under Table 1-1 for supplemental requirements to be addressed. This is no reduction in commitment. The project has chosen to apply NQA-1 to activities as part of the Quality Assurance Provisions Document, and those attributes are described in that document. The requirement is to develop a QAP consistent with the requirements of 10 CFR 830.120 for this application. Our integration of the requirements is consistent with revision 4.</p> |
| 4. | <p>Section 1.2.1, third paragraph – The sentence "Structures, systems, and components that serve to provide reasonable assurance that the facility can operate without undue risk to the health and safety of the workers and the public are considered Important to Safety."</p> <ul style="list-style-type: none"> • What is the relationship between "Important to Safety" and the safety classes (i.e., Safety Design Class and Safety Design Significant) described in the subsequent paragraphs of the QAPIP? • What is the purpose of introducing the term "Important to Safety" in Section 1.2.1 since it does not appear to be tied into the safety classes or quality levels in any way? | <p>Important to Safety is also defined in the DOE Top Level Standards and Principles. This approach is consistent with the definition.</p> <ul style="list-style-type: none"> • See revised text on quality classification. • See revised text on quality classification. Important to safety is an aspect of safety that the project has determined to use. |

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| 5. | <p>Section 1.2.1, fifth and sixth paragraphs – The word "graded" was added (i.e., "Table 1-2 represents a tabular summary of the <i>graded</i> application of QAP requirements for QL-1, QL-2 and QL-3 SSCs."</p> <p>The revised wording of this sentence thoroughly confuses the difference between QA classification and grading. Contrary to the implication of the revised wording, Table 1-2 represents <i>QA classification</i>, and shows the QA requirements that would apply to each safety class or quality level if no subsequent QA grading is performed. <i>QA grading</i> comes into play when the nine QA grading factors (identified by the bullets in the fifth paragraph) are weighted on an SSC-by-SSC basis to specifically determine the extent to which the QA controls should be applied to each SSC. For example, when considering the fourth grading factor, a specific SSC that is simple with respect to its design and fabrication would typically require fewer controls than an SSC that is complex. Similarly, if the functional compliance of an SSC can be fully demonstrated through inspection or testing (ninth grading factor), little or no QA controls may be required for that SSC, even though it may be classified as QL-1. Explain the approach BNFL will use to implement the nine QA grading factors identified in the fifth paragraph.</p> | <p>See revised text on QA classification and grading. Table 1-2 has been removed from the proposed revision based on this comment and the table contains information that is procedural detail in nature and not necessary for quality program use.</p> <p>Safety class determination and QA Classification is a process that occurs in the aspects of the design and safety processes for the selection of standards, hazard assessment, selection of control strategy and determination of consequence based on risk and anticipated frequency of events and the frequency that an SSC will have to function or perform its function. Classification is in the selection of those SSCs that meet the criteria for performance, function and control of important to safety SSCs.</p> <p>Table 1-2 did not provide classification, only QA criteria to be applied to SSCs once the classification occurs. The Table either applied a full QA program or partial QA program.</p> <p>The QA program is not the place to explain the BNFL approach to QA grading. Implementing documents and activities will accomplish the stated activity and provide a adequate level of safety and quality assurance implementation for the project.</p> |
| 6. | <p>Section 1.2.3.1, first paragraph – The last sentence mentions a "Quality Assurance Requirements Specification". It isn't clear what this document is, and why it does not appear on Figure 1-2 as might be expected.</p> | <p>The requirements specification is as stated, a document developed for project work that applies to subcontractors performing work. The specification does appear in Figure 1-2 as a product needed to complete project/business needs. Specifications are listed.</p> |

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| 7. | <p>Section 1.2.3.2, first paragraph – The last sentence (i.e., "Determination of QA classification shall be based on the design safety classification through accident analysis, safety reviews, and reliability, availability, maintainability analysis.") was deleted. This sentence should be retained since it explains the following:</p> <ul style="list-style-type: none"> • The linkage between safety classification and quality classification, and • How the safety classifications of SSCs are derived. | See new section on QA classification. |
| 8. | <p>Sections 1.2.3.2, third paragraph, and 2.2, second paragraph – These sections have diluted the orientation training for employees as follows:</p> <ul style="list-style-type: none"> • The revised wording has deleted job-specific QA orientation (i.e., ". . . advised of their individual roles in the program . . ." and ". . . each individual's role in the quality program . . ."); and • The revised wording changed a "complete understanding" of the quality program to familiarization with key elements of the quality program. <p>Employees should be given orientation regarding their job-specific roles in the QA program.</p> | <ul style="list-style-type: none"> • See revised section and paragraph. • As discussed in the response to the RU finding on the training. The indoctrination or orientation of personnel could never provide a complete understanding of the program and the use of the word "complete" in this context is subjective at best. This change was described in the change basis and the wording previously discussed with the RU. A "job specific" orientation is not in Section 2, 2.2, 2nd paragraph of Revision 4. The responsibilities of project personnel for the quality of their work provides the correct context for the individuals role in the program. Wording strengthened. |

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| 9. | <p>Section 1.2.3.5, first paragraph – The change to this section related to the QC organization reporting to the Construction Manager is not acceptable for the following reasons:</p> <ul style="list-style-type: none"> • It significantly diminishes or reduces a commitment made to date by BNFL to the Regulatory Unit regarding an important QA-related reporting relationship; • There is no information presented in the QAPIP justifying the proposed change (e.g., with respect to describing the measures and controls that will be used to ensure that adequate independence of the QC function will be achieved; • Figure 1-3 does not show the reporting relationship of either the Construction Manager nor the Construction QC organization; and • There is inadequate information contained in the QAPIP explaining the responsibilities of the Construction Manager as they relate to quality. | <p>The change is accurate in that the construction QC organization as part of a QA organization will report to the Construction manager. The final structure of the construction activities will be provided in the QAP revision associated with the construction submittal. Oversight of the construction QC organization by the BNFL Inc. QA organization and by the Constructor QA organization will occur.</p> <ul style="list-style-type: none"> • There is no commitment made in the QAP addressing this relationship. The construction QC and QA relationship remains valid. The construction QC organization will be part a construction QA organization. The exact reporting structure has yet to be fully developed. The BNFL Inc. QC organization is not addressed as the structure is still in development and will be provided to the RU in the construction submittal. The BNFL Inc. QC organization will report to the BNFL Inc. QA manager. The QA and QC organizations shall comply with the organizational requirement of 10 CFR 830.120 and the general good practice that the reporting level be at the same or higher organizational level as the line manager directly responsible for performing work. The QA organization for the construction activities has yet to be determined based in contract requirements and reporting relationships. • Proposed organizational charts indication independence will be provided with the QAPIP revision for construction. Wording changed to reflect this. • Figure 1-3 revised to show construction manager. Construction QC not necessary for this revision. • The Construction Managers' responsibility for quality will be full explained in the submittal for construction. |

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| 10. | <p>Section 1.3 - Inspections are quality control functions that are normally assigned to an organization's QA Manager. We suggest that BNFL Inc. should:</p> <ul style="list-style-type: none"> • Justify assigning the responsibility for vendor shop inspections and field receipt inspections to the procurement manager who may have conflicting cost and schedule responsibilities; and • Indicate why these inspections are not addressed in Section 8, Inspection and Acceptance Testing. | <p>See revised wording reflecting the responsibilities for the procurement function.</p> <ul style="list-style-type: none"> • Inspections and test activities for any function follow Section 8 requirement (see 8.1). |
| 11. | <p>Section 1.3, first paragraph – The wording was changed such that the General Manager is no longer responsible for the overall implementation of the QAP. Instead, his/her responsibilities have been restricted to compliance with the project quality policy. This could be interpreted as restricting his/her responsibility to the one page of "motherhood" in the quality policy statement versus the previous global commitment to be responsible for the overall implementation of the QA program.</p> | <p>See revised section on responsibilities.</p> |
| 12. | <p>Section 1.3, (TWRS Privatization Project Procurement Manager) – This section does not address the QC responsibility.</p> | <p>See revised responsibility section.</p> |

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| 13. | <p>Section 1.5, first paragraph – These changes reduce the scope of the annual QA program review to where it no longer includes a review of the implementing project procedures. Instead, it substitutes a review of the following:</p> <ul style="list-style-type: none"> • The "Implementation Plan", and • <u>Changes to</u> " . . . identified implementing documents . . .". <p>This wording is unacceptable since the purpose of the annual QA program review is to evaluate the QA program as a whole for conformance with applicable regulatory and quality requirements. Just reviewing the changes to the implementing procedures does not accomplish this. How would a review of just the changes to the procedures reveal whether or not the procedures themselves still conform to applicable regulatory and quality requirements?</p> | <ul style="list-style-type: none"> • The change was made to reflect that the implementing project procedures are developed and maintained under the QAP. The procedures once developed to complete the Implementation Plan may be revised to incorporate deleted, changed, new, additional or other material consistent with implementing documents that require review and approval. The review of changes to implementing documents will identify the changes proposed to be made to the established program and documents. It is similar to the chicken and egg discussion. The procedures are developed and approved, the QA manager is not responsible to determine that all implementing documents or procedure still comply with the applicable regulatory and quality requirements (other than his or her own procedures). That function remains the responsibility of the managers preparing, approving and using the implementing documentation. |
| 14. | <p>Section 2.2, second paragraph – Training of project personnel on the QAP should be provided to personnel with new job responsibilities. Training on QA responsibilities should be job-specific.</p> | <p>See revised paragraph on training.</p> |

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| 15. | Section 2.2, third paragraph – The changes to this section allow project personnel to work under supervision while they complete their training. This statement is confusing since all project personnel perform work under supervision. It also conflicts with the previous sentence (i.e., "Project personnel shall receive necessary training before their start of work"). These changes could lead to a practice whereby personnel do not complete their training for months or years. Training should be completed before personnel do quality-affecting work. Reword this section to eliminate these problems. | The ability to work under supervision while training is a primary principle of On the Job training. In addition, the common best management practice is to assign authority and responsibility appropriate to level of qualification, experience and training. The use of personnel while in training under supervision of their manager is routinely allowed. Specific requirements for special processes obviously do not allow full application, but the principle is the same. You learn by doing. Part of the training evolution requires performance. The section has been reworded, but the comment misses the point of on the job training. |
| 16. | Section 2.3, second paragraph – The last sentence states that a training matrix shall be maintained for tracking the training of personnel. Who is responsible for maintaining this training matrix? | See responsibilities in Appendix A.. |
| 17. | Section 3.2.1, fourth paragraph – The change proposes to delete a sentence that currently requires the CAMS database to record action planned to correct the condition/deficiency, responsible manager, date the condition was identified, date the condition is scheduled for completion, and completion date. These specifics are important aspects of a CAR tracking database. Justify why this information should be deleted. | These items are procedural level of detail and not necessary for the QA program. The implementing methods to accomplish the program belong in implementing documents. The CAMS database is open to the RU for inspection and review under the Corrective Action Program. The database provides the tools needed by the project to accomplish work. The delineation of details here is inappropriate. |
| 18. | Section 3.2.2, first paragraph – Clearly differentiate between the actions taken for Conditions Adverse to Quality (CAQ) and Significant Conditions Adverse to Quality (SCAQ). The wording added to this section indicates that SCAQs only are documented and reported to management. CAQs should also be documented and reported to management. Justify why this is only required for SCAQs. | See revised text on conditions adverse to quality. |

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| 19. | Section 3.2.2, second paragraph – The QAPIP uses the term "Root cause analysis (RCA) . . .". Does BNFL plan to use the formal root cause analysis methods (e.g., MORT), or merely conduct analysis for root cause? | Method to be developed. Method to be implemented by documents as specified in Implementation Plan. Revised wording. |
| 20 | <p>Section 4.2.3, first paragraph – The change deleted the provision requiring maintenance of records in remote, duplicate locations. Furthermore, a new second paragraph was added that states, in part: "QA records shall be temporarily stored in a container or facility with a fire rating of one hour, or dual storage will be provided." These changes are unacceptable since they make dual storage in remote, duplicate locations optional, allowing temporary storage in a one-hour fire-rated container.</p> <p>BNFL commits to complying with Part 1 of ASME NQA-1-1994 Edition. NQA-1 requires that records be stored in either:</p> <ul style="list-style-type: none"> • A single storage facility (Section 4.4.1 of Part 1 of NQA-1). [Note that a single storage facility must meet a number of stringent measures that are not required for temporary storage, including a two-hour fire rating.] or • Dual storage facilities located sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard (Section 4.4.4 of Part 1 of NQA-1). | Table 1-1 specifies the application of NQA-1 requirements. In addition, the use of records as described in 36 CFR Part 1220 provides that the current record generation set for the project is either contingent or unscheduled by federal record standards. |
| 20. cont. | <p>Section 4.4.3 of Part 1 of NQA-1 describes the requirements for temporary storage. As the name implies, these provisions are only applicable when temporary storage of records (i.e., for processing, review, or use) is required. NQA-1 does not intend completed records to be placed in temporary storage (i.e., single storage facility or in dual storage facilities) as a substitute for long-term storage.</p> <p>In summary, consider the following:</p> | <p>Permanent (project records have not been classified as such and DOE has the responsibility following deactivation for those records accepted in the Deactivation Plan) records under federal record storage disposition rules (36 CFR Part 1228.182) are normally transferred to the archive when:</p> <ul style="list-style-type: none"> • They are 30 years old, • At any age when the originating agency no longer needs to use the record for the purpose for which they were created or in its |

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| | <ul style="list-style-type: none"> • BNFL had previously committed to storing records in dual storage facilities; • The draft QAPIP currently under review deleted this provision; • BNFL now commits to only the temporary storage of records or dual storage; • Temporary storage is, as the name implies, only for the interim, short-term storage of records; and • Temporary storage is not a suitable substitute for the requirements to store completed records in either a single storage facility or in dual storage facilities. <p>Accordingly, the proposed approach is unacceptable because it implies that records could be stored indefinitely for long periods of time in a one-hour fire-rated temporary storage container rather than in either the required single storage facility or in dual storage facilities.</p> | <p>regular current business use; or the agency needs will be satisfied by the use of records in research rooms or copies of the records. (Additional wording in section)</p> <ul style="list-style-type: none"> • Based the federal storage and transfer requirement and the fact that the records will be needed for the purpose for which they were created and in the projects regular current business use for the life of the project. Storage in one hour fire proof cabinets exceeds the federal storage requirement for records prior to transfer to a federal storage facility or to the national archive. The project has no requirement to meet federal storage requirements in the contract. • Temporary records by federal standards is not short term, but records that have not been determined to have sufficient value to warrant preservation by NARA. Most of this projects' records will most likely be Temporary. • Temporary storage in NQA-1 included processing, review or use. As such, the records will be needed for the purpose for which they were created and in the projects regular current business <u>use</u> for the life of the project <p>The current DOE order for information management (DOE O 200.1) Attachment 1, Contractor Requirements Document, states that under the terms of their contract, contractors shall perform the following.</p> <p>1) Manage information management activities in accordance with applicable laws, regulations, and Department policy and manuals as identified in their contract, including any additional explicit Department information management requirements transmitted by the responsible Contracting Officer. 2) Employ sound business practices for information management to achieve performance objectives identified in their contract, and 3) Conduct funded programmatic information management activities in accordance with work scope agreed with Program Offices or customers. Item 1 and 2 are the key issues here as the contract does not specify storage</p> |

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| | | requirements and sound business practice is as proposed. Nothing in this section prevents BNFL Inc. from using dual storage as a best business practice should the business decide that this is needed.. The requirement for dual storage is not evident. |
| 21. | Section 5.3.1, second paragraph – The field activities described in the first sentence appear to go above and beyond those items which are usually assigned to the field organization under the direction of the Construction Manager (e.g., startup, operations, operations maintenance support, and deactivation). Reconsider this. | See revised section wording. During the construction phase, there will be some overlap or activities and the construction manager may provide assistance to some groups such as operations maintenance support. |
| 22. | Section 5.3.1, second paragraph – The last sentence refers to "field" subcontracts. Specify any differences between "field subcontracts" and other subcontracts. Are QA requirements imposed in like manner in both? | The word field deleted. |
| 23. | Section 5.3.4 – This section addresses "special processes"; however, no specific examples are provided. The QAPIP should include a list of typical processes that are considered to be "special processes". | Examples provided |
| 24. | Section 5.3.5 – What activities are considered "scientific investigations"? Do these include site pre-construction activities? Is the contracted GTS-Duratek work considered to be a scientific investigation? Please provide a list for clarification. | Section revised. The details of the activity belong in implementing documents, not in the QAP. Pre-construction activities may be included if the investigation involves scientific investigation. See QARD definition. Some of the GTS-D work at Catholic University is being completed under the QA provisions for this attribute. List to be discussed. |
| 25. | Section 6.2.13, first paragraph – Where did the NQA-1 reference come from? Also, the sentence " . . . is used as guidance for software quality requirements, as applicable," appears confusing. How are requirements used as guidance? | The NQA-1 reference is one of the supplementary requirements referenced in Table 1-1. The use of a "requirement" to provide guidance is part of a graded application and tailoring of activities to the defined need. |

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